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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/361,655 | 07/27/1999 | SE-JIN LEE | JHU1220-4 | 5790 |

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EXAMINER

MERTZ, PREMA MARIA

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| ART UNIT | PAPER NUMBER |
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1646

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DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/361,655

Applicant(s)

Lee et al.

Examiner

Premia Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 20, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 18-22, and 44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 18-22, and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

1. The request filed on 12/20/01 in Paper No. 12, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/361,655 is acceptable and a CPA has been established. An action on the CPA follows.

2. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 12, 12/20/01:

- (i) the rejection of claims 15-16, 18-22, under 35 U.S.C. § 101
- (ii) the rejection of claims 15-16, 18-22, under 35 U.S.C. § 112, first paragraph.

3. Applicant's arguments filed in Paper No. 12 (12/20/01), have been fully considered and were persuasive.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 15, 18-22, 44, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting the presence of GDF-12 in a liver specimen polypeptide in a liver specimen using an antibody, does not reasonably provide enablement for a method of detecting a liver cell proliferative disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

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Claim 15 recites "wherein the difference is indicative of a liver cell proliferative disorder", however, the specification is only enabling for a method for detecting the presence of GDF-12 in a liver specimen polypeptide in a liver specimen using an antibody. Applicants have not taught how the difference in expression between GDF-12 between a liver specimen from a subject and a control sample is indicative of liver cell proliferative disorders. The rejection of claim 15 can be obviated by reciting the specific liver cell proliferative disorders enabled by the specification. The specification does not enable the detection of all the various liver cell proliferative disorders encompassed by the claims. Furthermore, the claims recite "liver cell proliferative disorders" but the specification does not disclose or provide guidance as to what these "liver cell proliferative disorders" are, which requires a great deal of guidance regarding interpreting the results obtained by the claimed method. The specification fails to provide sufficient guidance because it is unpredictable what the expression of GDF-12 in "liver cell proliferative disorders" are relative to a control sample. Furthermore, with respect to claim 44, the specification does not disclose or provide guidance as to what the abnormal expression of GDF-12 is. Without this guidance, it would require undue experimentation to practice the invention as claimed.

Claims 18-22 are rejected under 35 U.S.C. § 112, first paragraph insofar as they are dependent on claim 15 for its limitations.

Claim rejections under 35 U.S.C. § 112, second paragraph

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5. Claims 15, 18-22, 44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite because it recites "liver cell proliferative disorder". It is suggested that the claim be amended to recite the disorder as supported by the specification.

Claim 44 is indefinite because it recites "abnormal expression". It is suggested that the claim be amended to recite the disorder as supported by the specification.

Claims 18-22 are rejected under 35 U.S.C. § 112, second paragraph insofar as they are dependent on claim 15 for its limitations.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
January 17, 2002